

Environmental Protection Agency

§ 63.10420

APPLICABILITY AND COMPLIANCE DATES

§ 63.10382 Am I subject to this subpart?

(a) You are subject to this subpart if you own or operate an ethylene oxide sterilization facility at a hospital that is an area source of hazardous air pollutant (HAP) emissions.

(b) The affected source subject to this subpart is each new or existing sterilization facility.

(1) An affected source is existing if you commenced construction or reconstruction of the affected source before November 6, 2006.

(2) An affected source is new if you commenced construction or reconstruction of the affected source on or after November 6, 2006.

§ 63.10384 What are my compliance dates?

(a) *Existing source.* If you have an existing affected source, you must comply with applicable requirements in this subpart no later than December 29, 2008.

(b) *New source.* If you start up a new affected source on or before December 28, 2007, you must comply with applicable requirements in this subpart by December 28, 2007.

(c) *New source.* If you start up a new affected source after December 28, 2007, you must comply with applicable requirements in this subpart upon start-up of your affected source.

STANDARDS

§ 63.10390 What management practice standard must I meet?

You must sterilize full loads of items having a common aeration time, except under medically necessary circumstances, as that term is defined in § 63.10448.

INITIAL COMPLIANCE REQUIREMENTS

§ 63.10400 How do I demonstrate initial compliance?

(a) Except as provided in paragraphs (b) and (c) of this section, you must demonstrate initial compliance with the management practice standard in § 63.10390 by submitting an Initial Notification of Compliance Status certifying that you are sterilizing full loads

of items having a common aeration time except under medically necessary circumstances.

(b) If you operate your sterilization unit(s) with an air pollution control device pursuant to a State or local regulation, you may demonstrate initial compliance with § 63.10390 by submitting an Initial Notification of Compliance Status certifying that you are operating the sterilization unit in accordance with your State or local regulation and following control device manufacturer's recommended procedures.

(c) If you operate your sterilization unit(s) with an air pollution control device but are not subject to any State or local regulation, you may demonstrate initial compliance with § 63.10390 by submitting an Initial Notification of Compliance Status certifying that you are venting the ethylene oxide emissions from each sterilization unit to an add-on air pollution control device. You must certify that you are operating the control device during all sterilization processes and in accordance with manufacturer's recommended procedures.

§ 63.10402 By what date must I demonstrate initial compliance?

You must demonstrate initial compliance with § 63.10390 upon startup or no later than 180 calendar days after your compliance date, whichever is later.

MONITORING—CONTINUOUS COMPLIANCE REQUIREMENTS

§ 63.10420 How do I demonstrate continuous compliance with the management practice requirements?

For each sterilization unit not equipped with an air pollution control device, you must demonstrate continuous compliance with the management practice standard in § 63.10390 by recording the date and time of each sterilization cycle, whether each sterilization cycle contains a full load of items, and if not, a statement from a hospital central services staff, a hospital administrator, or a physician that it was medically necessary.